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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,537	04/16/2001	Carl R. Merril	PNC-004	5407

61223 7590 02/07/2008

PANACEA PHARMACEUTICALS, INC.
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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/835,537	MERRIL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21-30 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21-30,33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. Rejection of claims 19,21-35 under 35 USC 112, 1st paragraph and rejection of claims 19,22-25,27-29 under 35 USC 102(e) and 103(a) as being anticipated by / obvious over Kaddurah-Daouk will not be maintained in light of amendment filed 11/27/06 for reason on record and reason as follows. Applicant argues that no structure for guanidine acetate exists. Examiner argues the claims comprise a guanidine salt, which would include guanidinoacetate. Guanidinoacetate is assumed to be guanidine acetate absent a showing that the structures differ. For this reason the rejections on record are maintained.

Response to Applicants' amendment

Examiner guanidinoacetate is not a guanidine salt. The prior art does not read on the instant claims.

II. Rejection of claims 19,23-29,31 under 35 USC 102(b) and 103(a) as being anticipated by and obvious over Azumendi in light of amendment filed 11/27/06 will not be maintained for reason on record and reason as follows.

Applicant argues that Azumendi

a) teaches treating prion diseases in mammals by administering NaI or KI to the mammals. (The aspect of hyperthermia being induced by NaI or KI is not understood). Hyperthermia is an optional component of treatment in accordance with the present invention; and

b) cannot be interpreted as disclosing a method for treating prion diseases (BSE or CJD) by administering NaI or KI (Azumendi speculates the treatment will be effective against BSE and CJD).

Examiner argues that

c) both Azumendi and instant invention discloses the same active step, i.e., administering chaotrophic agents (KI or NaI) to mammals. Therefore since both inventions disclose identical active step, it is inherent that both inventions would induce hyperthermia; and

d) Azumendi clearly expresses that KI or NaI is administered to mammals to treat prion diseases such as BSE or CJD. See abstract, page 5 lines 17-20, claim 1.

Response to Applicants' amendment

Claims have been amended to exclude KI and NaI. The prior art cited no longer reads on the instant claims.

New Rejections

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19,21-30,33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation, "suffering from or susceptible to a prion disease" in the claims appears to be new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,21-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Keana (USPN 5385946; 1/31/95). Keana teaches a method of treating hypertension in a mammal comprising administering to the mammal a guanidine HCl (0.0025 to 15 mg / kg). See column 18 lines 18-36 and claims in USPN '946. The instant claims recite that the guanidine salt is administered to a mammal that is susceptible to prion disease. Interpreting the claims broadly, a person suffering from hypertension may be susceptible to prion disease.

Claim Objection

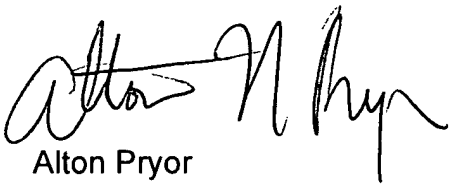
Claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant invention comprising microwave energy or bacterial toxins.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton Pryor
Primary Examiner
AU 1616